STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
MOHAMED HASSEN, R.PH.	)	
License No. 2001029694	)	Complaint No. 2016-007438
4029 Blaine Avenue	)	
St. Louis, MO 63110	)	

SETTLEMENT AGREEMENT BETWEEN THE MISSOURI BOARD OF PHARMACY AND MOHAMED HASSEN

Come now Mohamed Hassen, R. Ph. ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license to practice pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that he understands the various rights and privileges afforded him by law, including the right to a hearing of the charges against him; the right to appear and be represented by counsel; the right to have all charges against him proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against him; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against him and, subsequently, the right to a disciplinary hearing before the Board at which time he may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against his license. Being aware of these rights provided him by operation of law, Respondent knowingly

and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to him.

Respondent acknowledges that he has received a copy of the draft Complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license to practice pharmacy, numbered 2001029694, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo[1], for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Mohamed Hassen ("Respondent") is licensed as a pharmacist under the laws of the State of Missouri, License No. 2001029694. Respondent's license was at all times relevant herein current and active.

3. At all relevant times herein, Respondent was employed at Barnes-Jewish Hospital Pharmacy located at One Barnes-Jewish Hospital Plaza, St. Louis, MO 63110 (the "Pharmacy").

4. On December 30, 2016, the Board office received a letter from the Pharmacy reporting corrective disciplinary action issued to Respondent for providing an unauthorized prescription medication to an employee.

[1] All statutory references are to the Revised Statutes of Missouri 2016 as amended unless otherwise indicated.

5. Board Inspector Katie DeBold investigated the incident on behalf of the Board.

6. In February, 2017, Respondent admitted to Inspector DeBold both verbally and in writing that on November 26, 2016, he gave a technician at the Pharmacy one 4 mg tablet of Zofran ODT because she was repeatedly throwing up and was unable to swallow anything.

7. Zofran ODT is a prescription medication.

8. The pharmacy technician did not have a prescription for Zofran ODT 4mg.

Misbranding

9. Section 196.015(1)-(2), RSMo prohibits misbranding of drugs in the State of Missouri, to wit:

> The following acts and the causing thereof within the state of Missouri are hereby prohibited:
>
> > (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
> >
> > (2) the adulteration or misbranding of any food, drug, device, or cosmetic;

10. Misbranding of a drug under Missouri law is defined in § 196.100.1, RSMo, which states in pertinent part:

> 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

11. A legend drug is misbranded under 21 U.S.C. §353(b)(1) of the Federal Food, Drug and Cosmetic Act, as amended, under the following circumstances:

> (b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which –

> (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
>
> (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

12. Federal law also prohibits:

> (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any . . . drug . . . in interstate commerce.
>
> 21 U.S.C. § 331(a)-(b).

13. Respondent's dispensing of Zofran ODT to another without a prescription and without the requisite labeling constitutes misbranding in violation of §§ 196.100, .015, RSMo, and 21 U.S.C. §§ 331, 353.

Failing to label drug

14. Missouri law requires that pharmacists affix a label to every container in which a prescription drug is dispensed, to-wit:

> 1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist's or physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug or biological product upon which is typed or written the following information:
> (1) The date the prescription is filled;
> (2) The sequential number or other unique identifier;
> (3) The patient's name;
> (4) The prescriber's directions for usage;
> (5) The prescriber's name;
> (6) The name and address of the pharmacy;
> (7) The exact name and dosage of the drug dispensed;
> (8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill";
> (9) When a generic or interchangeable biological substitution is dispensed, the name of the manufacturer or an abbreviation thereof shall appear on the label or in the pharmacist's records as required in section 338.100.
>
> § 338.059.1, RSMo.

15. Respondent violated § 338.059.1, RSMo, by dispensing of Zofran ODT without a label containing the information required by § 338.059.1, RSMo.

Failure to make and keep records

16. Missouri law requires that pharmacists verify the accuracy of electronic prescription data for each prescription prior to dispensing:

> (1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally

verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

(2) EDP systems shall comply with the requirements of section 338.100, RSMo, and shall be capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:
(A) A unique, sequential prescription label number;
(B) If applicable, a unique readily retrievable identifier;
(C) Date the prescription was prescribed;
(D) The date the prescription was initially filled and the date of each refill;
(E) Patient's full name, or if an animal, the species and owner's name;
(F) Patient's address or animal owner's address when a prescription prescribes a controlled substance;
(G) Prescriber's full name;
(H) Prescriber's address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;
(I) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
(J) Quantity originally dispensed;
(K) Quantity dispensed on each refill;
(L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
(M) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;
(N) The number of authorized refills and quantity remaining;
(O) Whether generic substitution has been authorized by the prescriber;
(P) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and
(Q) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(3) The information specified in section (2) shall be required and recorded in the EDP system prior to dispensing by a pharmacist or pharmacy.

20 CSR § 2220-2.080(1)-(3), RSMo.

17. Respondent violated 20 CSR § 2220-2.080(1)-(3), RSMo, by dispensing Zofran ODT to another without a prescription and without recording prescription information for the drug into the Pharmacy's EDP system.

Cause to Discipline

18. Respondent's conduct is cause for disciplinary action against his license to practice pharmacy under § 338.055.2(5), (6), (13) and (15), RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> * * *
>
> (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
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> * * *
>
> (13) Violation of any professional trust or confidence;
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> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

A. Respondent's license, License No. 2001029694, is hereby **PUBLICLY CENSURED.**

B. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

C. Respondent, together with his heirs and assigns, and his attorneys, does hereby waive and release the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____REQUESTS

MH DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE TO PRACTICE PHARMACY.

The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

MOHAMED HASSEN

Mohamed Hassen

Mohamed Hassen

Date: 10-17-2017

PETITIONER

MISSOURI BOARD OF PHARMACY

By:

Kimberly Grinston
Executive Director

Date: 11/9/17

NEWMAN, COMLEY & RUTH P.C.

By:

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